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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Docket Number (Optional)** PRE-APPEAL BRIEF REQUEST FOR REVIEW 01942-00007 Application Number I hereby certify that this correspondence is being transmitted to the United States Postal Service electronically December 4, 2001 addressed to "Mail Stop AF, Commissioner for 10/006,796 O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] First Named Inventor Eija M. Pirhonen Signatur Art Unit Examiner Typed or printed Micah-Paul Young 1618 Laurie Hall Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. assignee of record of the entire interest. Iwanicki See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. Typed or printed name (Form PTO/SB/96) attorney or agent of record. 34.628 (617) 720-9600 Registration number Telephone number attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.

*Total of forms are submitted. This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to

Submit multiple forms if more than one signature is required, see below*.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
Eija Marjut Pirhonen, Timo Pohjonen, and Jan Nieuwenhuis)	Examiner: Micah-Paul Young
Serial No.:	10/006,796)	Art Unit: 1618
Filed:	December 4, 2001)	Conf. No.: 9843
Title: BIODEGRADABLE IMPLANT AND METHOD FOR MANUFACTURING ONE)))	

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

REASONS IN SUPPORT OF REQUEST FOR PRE-APPEAL BRIEF REVIEW

Applicants respectfully request pre-appeal brief review for the following reasons.

In the present final Office Action dated September 22, 2006 and in view of the Advisory Action mailed December 19, 2006 responding to Applicants' Amendment and Response filed September 22, 2006, the Examiner has clearly erred by failing to identify where in Freeman the claim structural limitations of the implant having the plasticizer dispersed within the rigid matrix and a porous surface and a substantially nonporous core are found. The final office action also incorrectly rejects the amendment to the claims requiring a substantially nonporous core as being new matter. Finally, the final office action incorrectly relies on product-by-process considerations in rejecting the claims.

In the Response dated November 22, 2006 at pages 9-11, the Applicants reaffirm that the claimed implant requires the recited structure and composition of a rigid matrix and a plasticizer (N-methyl-2-pyrrolidone in particular for certain claims) dispersed within the rigid matrix and also requires a porous surface and a substantially nonporous core. Regarding the anticipation rejection of claims 1-4 and 6-8 based on Freeman at pages 3-4 of the present final office action of September 22, 2006, nowhere in the final office action does the Examiner state where Freeman discloses the presence of the claimed plasticizer dispersed within the rigid matrix. Instead, the Examiner has improperly ignored the clear presence of the claimed plasticizer dispersed within the rigid matrix, stating that it is not material to patentability. However, in an anticipation rejection, the Examiner cannot ignore claim limitations. The reference cited by the Examiner must teach each and every claim limitation expressly or inherently. The Examiner has identified no express teaching of the claimed plasticizer in Freeman and has stated no reasoning why the claimed plasticizer is necessarily present in Freeman. Accordingly, the Examiner's anticipation rejection of claims 1-4 and 6-8 based on Freeman is improper and should be withdrawn. Applicants note no other art rejections pending against claims 1-4 and 6-8.

Remaining claims 5 and 9-17 stand rejected at pages 4-5 of the final office action as being obvious over the combination of Freeman and Polson US 5,487,897. The Examiner notes in the final office action that Polson describes the use of N-methyl-2-pyrrolidone, but the Examiner does not identify in the final office action where Polson teaches NMP dispersed within a rigid matrix. Instead, Polson makes clear that the NMP is used as a solvent in an amount to form a liquid polymer solution. Col. 6 lines 45-58. NMP is not dispersed within a rigid matrix as claimed with the implant having a porous surface and a substantially nonporous core. See

pages 11-13 of the Amendment and Response filed September 22, 2006. Further, Polson does

not teach a porous surface with a substantially nonporous core. Polson, therefore, does not cure

the deficiencies of Freeman. Accordingly, Freeman and Polson do not create a prima facie case

of obviousness.

In response to the Examiner's rejection of claims 1-17 as including new matter as to the

claimed substantially nonporous core, applicants have addressed that rejection at pages 6-9 of the

Amendment and Response filed September 22, 2006. The final office action errs in not

considering whether one of skill in the art following the teachings of the as-filed specification

would understand that Applicants were in possession of the claimed invention at the time of

filing. Clearly, one of skill in the art would understand this, and accordingly, the Examiner's

rejection of the claims on new matter grounds is improper. Ipsis verbis recitation of claim

language in the specification is not a prerequisite to meeting the written description requirement,

and accordingly, a new matter rejection is improper when it is clear from the specification that

the Applicants' were in possession of the claimed invention at the time of filing when specific

examples recited in the specification are followed.

Based on the above, Applicants respectfully request a pre-appeal brief review.

Respectfully submitted,

Dated: <u>January</u> 22, 2007

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